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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,590,645

NOTICE OF FINAL DETERMINATION - INELIGIBLE

GlaxoSmithKline ("Applicant"), the present owner of record of U.S. Patent No. 5,590,645 ("the '645 patent"), filed, through the previous patent owner of record, Glaxo Group Ltd., an application ("PTE Application") for extension of the term of the '645 patent under 35 U.S.C. § 156 in the United States Patent and Trademark Office ("USPTO") on November 7, 1997. Applicant sought extension based upon the premarket review under section 505 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") of a human drug product known by the tradename SEREVENT® DISKUS® having the active ingredient salmeterol xinafoate. The Food and Drug Administration ("FDA") approved SEREVENT® DISKUS® for commercial use and sale on September 19, 1997.

A determination has been made that the '645 patent is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of SEREVENT® DISKUS®.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by Applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The FDA official records indicate that salmeterol xinafoate was previously approved for commercial marketing or use prior to the approval of SEREVENT® DISKUS®. In a letter dated December 14, 1998, FDA stated:

> A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd. 894 F. 2d 392 (Fed. Cir. 1990).

(Emphasis added).

Under 35 U.S.C. § 156(a), a term of a patent which claims a product shall be extended if, *inter*

alia, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under section 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

(Emphasis added).

Thus, the determination of eligibility of the '645 patent turns on the provisions in section 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredient in the approved product SEREVENT® DISKUS® is salmeterol xinafoate. As noted in the FDA's December 14, 1998, letter, and as stated at paragraph (4) on page 3 of the PTE Application, the active ingredient, salmeterol xinafoate, had been approved for commercial marketing and use prior to the approval of SEREVENT® DISKUS®. Further, the prior approval of the active ingredient, salmeterol xinafoate, by the FDA was under section 505 of the FFDCA, the same provision of law under which regulatory review of the product SEREVENT® DISKUS® occurred. Applying the definition of "product" provided in section 156(f) to the extension requirement of section 156(a)(5)(A), Applicant's product, SEREVENT® DISKUS®, does not qualify as the first permitted marketing or use of the active ingredient. Because the approval of SEREVENT® DISKUS® was not the first permitted marketing or use of the active ingredient thereof, salmeterol xinafoate, the patent is not eligible for patent term extension based upon the regulatory review of SEREVENT® DISKUS®. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

At paragraph (1) on page 3 of the PTE Application, Applicant states that extension of the '645 patent is sought "based upon the approval of the DISKUS® Inhalation Device, not the active ingredient of the drug product, salmeterol xinafoate." Later, at paragraph (4) on page 3 of the PTE Application, Applicant reiterates that "the active ingredient of SEREVENT® DISKUS®, salmeterol xinafoate, is not being relied upon as the basis for extending U.S. 5,590,645."

However, as stated above, the term of a patent which claims a product shall be extended under 35 U.S.C. § 156(a) if, *inter alia*, the product has been subject to a regulatory review period before its commercial marketing or use. The only regulatory review period of record upon which an extension under section 156(a) could be based is the regulatory review period under section 505(b) of the FFDCA for SEREVENT® DISKUS® (salmeterol xinafoate inhalation powder). In this regard, Applicant states at paragraph (2) on page 3 of the PTE Application that "[t]he Approved Product, SEREVENT® DISKUS®, was subject to regulatory review under Federal Food, Drug and Cosmetic Act, section 505 (21 U.S.C. § 355)." Further, although Applicant states at paragraph (1) on page 3 of the PTE Application that extension of the '645 patent is sought "based upon the approval of the DISKUS® Inhalation Device," Applicant has not identified a regulatory review period for a medical device, as defined in 35 U.S.C. § 156(g)(3)(B), upon which an extension under 35 U.S.C. § 156(a) could be based. Because the regulatory review period under section 505 of the FFDCA for SEREVENT® DISKUS® (i) constitutes the only regulatory review period of record upon which an extension under 35 U.S.C. § 156(a) could be based and (ii) is under the same provision of law under which the prior approval of the active ingredient salmeterol xinafoate on February 4, 1994, occurred, Applicant's product, SEREVENT® DISKUS®, does not qualify as the first permitted marketing or use of the active ingredient under the provision of law under which such regulatory review period occurred.

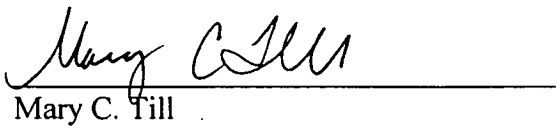
In view of the above, the term of the '645 patent is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product SEREVENT® DISKUS®, and the application for patent term extension, filed November 7, 1997, is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Term Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7728

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728. E-mail inquiries should be directed to Raul.Tamayo@uspto.gov.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
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for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: SEREVENT® DISKUS®
FDA Docket No.: 98E-0845